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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,021	11/26/2003	Keith M. Orr	22956-239	7261
21125 7590 08/03/2010 NUTTER MCCLENNEN & FISH LLP SEAPORT WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER				
DÖRNBUSCH, DIANNE				
ART UNIT		PAPER NUMBER		
3773				
NOTIFICATION DATE		DELIVERY MODE		
08/03/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

### Office Action Summary

**Application No.**

10/724,021

**Applicant(s)**

ORR ET AL.

**Examiner**

DIANNE DORNBUSCH

**Art Unit**

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 9-13, 15-18, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-13 and 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/888)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-7, 9-13, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (2004/0204715) in view of Reid (3,581,956)

Claims 1-6:

Evans discloses the following claimed limitations:

*Claim 1:* A first component (300) for receiving and dispensing the tissue scaffold having a funnel-shaped proximal end (320), a distal end (330), and an elongate, hollow body (310) extending therebetween (Fig. 2), the elongate body defining a passageway extending from the flared proximal end to the distal end (Fig. 5); and a second component (100) having an elongate body (110) with a blunt tip at a distal end (Fig. 2 and 5), the elongate body being configured to be removably disposed within the first component for sliding along the passageway (Fig. 1-2), the second component including at least one sealing ring (150) around the elongate body proximal to the tip (Fig. 2 and 5).

Regarding the statement that the first component is for receiving and dispensing the tissue scaffold and that the second component slides along the passageway, it has been held that a recitation with respect to the manner in which a claimed apparatus is

intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

*Claim 2:* Wherein the passageway includes a first, flared portion extending into a second, tubular portion (Fig. 5).

*Claim 3:* Wherein the first, flared portion has a curved tapered shape (Fig. 2 and 5)

*Claim 4:* Wherein the flared proximal end of the first component has a diameter in the range of about 15 mm to about 50 mm ([0048]).

*Claim 5:* Wherein the second, tubular portion has a diameter in the range of about 5 mm to about 17 mm ([0042]).

*Claim 6:* Wherein the tip of the second component comprises a spherical tip (Fig. 5)

Evans teaches all the claimed limitations discussed above however, Evans does not disclose that the tip has a diameter less than the diameter of the elongated body.

Reid discloses plunger (12) which includes a knob (58) at the distal end that has a diameter less than the diameter of the elongated member (28).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Evans with a knob at the distal end with a smaller diameter than the diameter of the elongated member in view of the teachings of Reid, in order to minimize the side of the bore of the first component ahead of the plunger, thereby providing greater accuracy of control of the discharge of the sample in the device.

Claim 7: Evans teaches all the claimed limitations discussed above however, Evans does not disclose that the spherical tip has a diameter in the range of about 6 mm to about 10 mm.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Evans with the diameter range since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Furthermore, the differences in concentration, temperature, size, or pressure will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration, temperature, size, or pressure is critical.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05 (II).

Claim 9: Evans discloses an insertion tube (300) having a funnel-shaped proximal end (320), a distal end (330) and a hollow passageway extending therebetween (Fig. 5); and an insertion rod (100) having an elongate shaft (110) extending into a handle (120) at a proximal end (Fig. 2) and a blunt tip at a distal end (Fig. 2 and 5), the elongate shaft being configured to be removably disposed within the insertion tube for sliding along the passageway (Fig. 1-2) and contacting the tissue scaffold disposed within the insertion device (the tip contact the material inside the passageway as it is being pushed out of the insertion tube); the insertion rod including a sealing ring (150) around the elongate shaft (Fig. 2 and 5).

Regarding the use of a scaffold and that the second component slides along the passageway, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Evans teaches all the claimed limitations discussed above however, Evans does not disclose that the insertion rod further includes a pair of sealing rings around the elongate body.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have a second sealing ring since the examiner is taking Official Notice that the use of a second sealing ring is well known in the art in order to control the sliding resistance between the first components and the second component as well as providing a seal.

Evans teaches all the claimed limitations discussed above however, Evans does not disclose that the tip has a diameter less than the diameter of the elongated body.

Reid discloses plunger (12) which includes a knob (58) at the distal end that has a diameter less than the diameter of the elongated member (28).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Evans with a knob at the distal end with a smaller diameter than the diameter of the elongated member in view of the teachings of Reid, in order to minimize the side of the bore of the first component ahead of the plunger,

thereby providing greater accuracy of control of the discharge of the sample in the device.

Claim 10: Evans discloses that the passageway includes a first, flared portion extending into a second, tubular portion (Fig. 2 and 5).

Claim 11: Evans discloses that the first, flared portion has a curved, tapered shape (Fig. 2 and 5).

Claim 12: Evans discloses that the second, tubular portion has a diameter in the range of about 6 mm to about 17 mm ([0048]).

Claim 13: Evans discloses all the claimed limitations discussed above except the second, tubular portion has a diameter in the range of about 7 mm to about 9 mm. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Evans with the diameter range since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim 15: Evans discloses that the flared proximal end of the insertion tube has a diameter in the range of about 15 mm to about 50 mm ([0048]).

Claim 16: Evans discloses that the blunt tip of the insertion rod comprises a spherical tip (Fig. 2 and 5).

Claims 17 and 18: Evans teaches all the claimed limitations discussed above however, Evans does not disclose that the spherical tip has a diameter in the range of about 6 mm to about 10 mm.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Evans with the diameter range since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Furthermore, the differences in concentration, temperature, size, or pressure will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration, temperature, size, or pressure is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05 (II).

### ***Response to Arguments***

3. Applicant's arguments with respect to claims 1-7, 9-13, and 15-18 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within



TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./

Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773